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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
PATEL, NATASHA	
ART UNIT	**PAPER NUMBER**
3766	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/18/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/829,544	ALMEN, ADAM J.	
	Examiner	Art Unit	
	Natasha N. Patel	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 October 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *28-76* is/are pending in the application.

4a) Of the above claim(s) *28-52* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *53-76* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The amendment filed on October 24, 2006 has been received and considered. By this amendment, Claims 1-27 are cancelled, Claims 28-52 are withdrawn, and Claims 53-76 have been added. Claims 53-76 are now pending in the application.

Drawings

2. In view of the Applicant's modifications to the drawings, the Examiner is withdrawing the objection, which was made against the drawings in the previous Office Action.

Claim Objections

3. In view of the Applicant's cancellation of Claims 24-26, the Examiner is withdrawing the objections, which were made against those claims in the last Office Action.

Response to Arguments

4. Applicant's arguments filed on October 24, 2006 have been fully considered but they are not persuasive. The claim language does not specify that the threshold must be non-predetermined. Furthermore, Halyak does evaluate heart rate variability since variability simply means 'changes' and Halyak discloses documenting changes (see col. 4, line 26) in heart rate (see col. 3, line 65) and analyzing the changes to calculate times of wakefulness (see col. 3, lines 12-16). Similarly, Amano discloses changes (see col. 3, lines 35-40) in physiological state (see heart rate; col. 1, lines 16-18) and the analysis of those changes (see col. 16, lines 52-63).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> **(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.**

6. Claims 53-61 and 65-68 are are rejected under 35 U.S.C. 103(a) as being unpatentable over Halyak et al. (US Patent 5,928,133) in view of Amano et al. (US Patent 6,126,595).

7. Regarding Claim 53, Halyak discloses a heart rate variability monitor (apparatus 10), comprising: at least two electrical contacts for detecting analog electrical signals generated within a body when placed in contact with the body (see sensor 12); a heart rate variability signal processor that monitors and analyzes the digital signal data and obtains heart rate variability data therefrom (see microprocessor 20); and a memory capable of storing real time digital signal data (see col. 4, lines 17-20). The examiner considers that apparatus 10 is a heart rate variability monitor because it monitors (see Claim 1, first part) physiological properties such as heart rate (see col. 3, line 65) and changes in heart rate (see Claim 3, part 3). Although Halyak does not teach that the monitor is wrist-worn, he does disclose that the top and bottom of the wrist have been used for physiological tests with success (see col. 4, lines 58-59). Furthermore, Halyak does not disclose a circuit that conditions the electrical signals and converts the analog electrical signals to digital signal data. However, it is common and well known to include

this signal-processing feature in physiological monitors. Amano teaches the conversion of analog signals to digital data (see A/D converter 444) in a similar wrist-worn monitor. Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention to digitize the data collected by the sensors for clearer signals that are easier to store. Amano also discloses a heart rate variability signal processor (controller 109) that monitors and analyzes the digital signal data for a defined time interval (see col. 3, lines 7-14), and calculates parameters comprising the mean digital signal value and at least one standard deviation of the digital signal data monitored and analyzed over the defined time interval (see col. 69, lines 11-18), and wherein the processor performs at least one heart variability test (see col. 16, line 25-col. 17, line 47). The examiner considers that determining the daily fluctuations is equivalent to performing a heart variability test because the changes in physiological parameters are being tested for a significant indication. It would have been obvious to one of ordinary skill in the art at the time of the invention to include a mean digital signal value and at least one standard deviation of the signal data because standard deviations are well-known in the signal processing art and Amano teaches the use of standard deviations as a buffer when determining whether or not to sound an alarm in the case of parameters being outside the predetermined range (see Abstract).

8. Regarding Claim 54, Halyak discloses that the processor performs at least one heart rate variability test including comparison of the digital data against calculated parameters (see col. 5, lines 26-29). The examiner considers that the predetermined threshold is a calculated parameter.

9. Regarding Claim 55, Halyak discloses that the analog electrical signals are generated by the heart (see col. 3, lines 65-66).

10. Regarding Claim 56, Halyak discloses that the parameters are awake parameters calculated over the defined time interval comprising the mean awake heart rate value (see col. 4, lines 30-31 and Figure 3). Halyak does not disclose that the parameter comprises at least one standard deviation thereof. However, see rejection of similarly worded Claim 1 above with regard to the standard deviations.

11. Regarding Claim 57, Halyak discloses the parameters comprise the mean non-REM heart rate value (see col. 4, lines 30-38). The examiner considers non-REM to be the spikes that occur at the beginning and end of the REM cycle because the Applicant discloses that non-REM occurs between the awake stage and the REM stage (see page 3, lines 2-5). As to the standard deviation, see rejection of similarly worded Claim 1 above.

12. Regarding Claim 58, Halyak discloses the parameters comprise the mean REM heart rate value (see 36; col. 4, lines 32-33). As to the standard deviation, see rejection of similarly worded Claim 1 above.

13. Regarding claim 59, see rejection of similarly worded Claim 56 above. Furthermore, Halyak discloses performing at least one heart rate variability test using awake parameters and recognize when the user has entered non-REM sleep (see col. 4, lines 30-38). The examiner considers that Halyak's device is constantly performing a heart rate variability test in order to determine whether the patient is awake, in non-

REM, or in REM. The test comprises of comparing the collected heart rate to the predetermined thresholds.

14. Regarding Claim 60, see rejection of similarly worded Claim 57 above. Furthermore, Halyak discloses performing at least one heart rate variability test using the non-REM parameters and recognize when the user has entered awake state (see 'spikes of activity' col. 4, lines 33-35) or REM sleep (see 36; col. 4, lines 32-33). Again, the examiner considers that Halyak's device is constantly performing a heart rate variability test (see reasons stated in the rejection of Claim 59).

15. Regarding Claim 61, see rejection of similarly worded Claim 58 above. Furthermore, Halyak discloses performing at least one heart rate variability test using the using the REM parameters and recognize when the user exits REM sleep (see end of REM cycle; col. 4, lines 33-35). The examiner considers that Halyak's device is constantly performing a heart rate variability test (see reasons stated in the rejection of Claim 59).

16. Regarding Claim 65, Halyak discloses a timer (see clock 18), wherein the timer is capable of timing the duration of the monitoring of the heart rate variability data (see col. 4, lines 15-17). The timer helps the microprocessor write the HRV data to memory at specified time intervals (see col. 4, lines 19-20). Thus, the timer is timing when to start and stop the monitoring-- in other words the duration of the monitoring. Although Halyak does not explicitly disclose time-stamping the data, the examiner considers that clock 18 automatically time-stamps the data being that the data would be useless to the user if it did not contain information about when each sleep stage occurred and how long

they lasted (see col. 4, lines 25-28). Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention to time-stamp the HRV data so that it can be analyzed afterwards.

17. Regarding Claim 66, Halyak discloses that the timer is capable of timing the duration of the heart rate variability test (see col. 4, lines 17-20). Since the heart rate variability test is performed during specified time intervals determined by the timer (clock 18), the duration is already timed and known.

18. Regarding Claim 67, Halyak discloses a waking prompt, but does not explicitly disclose that the waking prompt is activated when REM sleep is recognized. However, it would be obvious to one of ordinary skill in the art at the time of the invention, to activate the prompt at some point in the sleep cycle because the applicant has not disclosed an apparent advantage of waking the user up at the immediate start of REM over waking the user up some time before REM, during non-REM. Waking someone up during non-REM sleep is going to give similar results to waking someone up just as soon as REM is detected. If the applicant were merely trying to prevent grogginess, then waking up a patient during non-REM would do the same thing. In essence, activating the waking prompt when REM is recognized is an obvious choice by anyone looking to prevent grogginess.

19. Regarding Claim 68, Halyak discloses a processor that is capable of discerning and counting REM sleep state cycles and wherein the waking prompt is activated after a specified number of REM sleep state cycles are completed by a user (see col. 3, lines 27-33).

20. Claims 62-64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Halyak et al. (US Patent 5,928,133) and Amano et al. (US Patent 6,126,595), as applied to Claim 53 above, in view of Golosarksky et al. (US Patent 5,718,235).

21. Regarding Claims 62-64, Halyak is mainly concerned with the different stages of sleepfulness and wakefulness. Halyak does not disclose performing a heart rate variability test during physical activity. Golosarsky discloses a processor (see computer 104) and performing a heart rate variability test when the user is awake, active, and asleep (see col. 21, lines 46-50). It would have been obvious to one or ordinary skill in the art at the time of the invention to perform heart rate variability tests during all of these instances in order to take the patient's stress state into account so a more extensive determination of the patient's condition can be made (see col. 1, lines 60-63).

22. Claims 69-70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Halyak et al. (US Patent 5,928,133) and Amano et al. (US Patent 6,126,595), as applied to Claim 54 above, in view of Atlas et al. (US Patent 6,265,978).

23. Regarding Claim 69, Halyak discloses a processor capable of monitoring heart rate variability data during a user's sleep period (see block 52, Figure 4). However, Halyak does not disclose the detection of a sleep apnea event. Atlas discloses a similar wrist-worn monitor that can be used to identify sleep apnea (see col. 10, lines 1-3). Because Altas teaches that apnea detection would be particularly applicable in sleep monitoring, one of ordinary skill in the art at the time of the invention would have found it obvious to provide such a feature in Halyak's sleep monitor, which also seeks to provide

user's with information about their awakening points and sleep interruptions (see '133 col. 2, lines 64-68).

24. Regarding Claim 70, Halyak discloses a waking prompt, wherein the waking prompt is activated when physiological information is detected (see col. 3, lines 17-20). Halyak does not disclose that the physiological information may include the presence of apnea. Because Altas teaches that apnea detection would be particularly applicable in sleep monitoring (see col. 10, lines 1-3), one of ordinary skill in the art at the time of the invention would have found it obvious to incorporate a waking prompt in Halyak's sleep monitoring and awakening device especially since apnea would entail temporary wakefulness and according to Halyak, it would be optimal to prompt a person at an already wakeful time (see col. 4, lines 38-44).

25. Claims 71-73 are rejected under 35 U.S.C. 103(a) as being unpatentable over Halyak et al. (US Patent 5,928,133) and Amano et al. (US Patent 6,126,595), as applied to Claim 53 above, in view of Gomes et al. (US Patent 4,570,637).

26. Regarding Claims 71-73, Amano discloses the monitor having a back surface (see col. 23, lines 59-65). Amano does not disclose a porous, conductive membrane disposed on the back surface of the monitor and having contact with the user's skin to increase the monitor's ability to pick up the ECG signals. Nor does Amano disclose a conductive gel being incorporated into the pores of the conductive membrane to increase the monitor's ability to pick up the ECG signals. However, it is well known and common to incorporate these elements on a monitor having a sensor-type device especially because they are readily used with electrodes, whose main function is

picking up ECG signals. Gomes is cited for his use of an electrode having a porous, conductive membrane impregnated with a conductive gel to increase the conductivity of the electrode thereby making it easy to pick up signals (see col. 5, line 62- col. 6, line 7). Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention to apply the same materials used to enhance a single electrode to enhance the conductivity between Amano's monitor and the skin because the monitor relies on analyzing the ECG signals and the better the signals, the more accurate the analysis.

27. Claims 74-76 are rejected under 35 U.S.C. 103(a) as being unpatentable over Halyak et al. (US Patent 5,928,133) and Amano et al. (US Patent 6,126,595), as applied to Claim 54 above, in view of Lind et al. (US Patent 6,889,165).

28. Regarding Claim 74, Halyak does not disclose using his heart rate monitor to control appliances in a home. Lind discloses a wrist-worn smart sensor module that monitors heart rate and downloads the data to a remote computer (see col. 11, lines 40-55). Lind discloses home information paths from the wrist worn heart rate monitor to each room (see pico-mode controller 215, Figure 11); at least one home control unit receiver (see site node controller 230) connectable to the transmission paths, installed in selected rooms for transmitting and receiving information along the transmission paths. The examiner considers the home control unit receivers are capable of being in separate rooms even though it is not explicitly disclosed because the information paths use communications means that can handle remote information transmission. Lind also discloses a central home control unit (see central network node 235), connectable to the transmission paths, the at least one home control unit receiver and to appliances in the

rooms (see col. 12, lines 33-40). The examiner considers that the transmission paths can be established between the central home control unit and the appliances in the rooms as long as the appliances are smart appliances and have compatible sensor modules with which they can transmit/receive data. Lind does not disclose that the wrist worn heart rate variability monitor is capable of transmitting an awake signal or a sleep signal to the at least one home control unit receiver based upon heart rate variability data. Nor does Lind disclose that the control unit receives the awake or sleep signal transmitted by the at least one control unit receiver, wherein when an awake signal is transmitted to the appliances by the computer, the appliances are turned on and when a sleep signal is transmitted by the computer, the appliances are turned off. However, just as Lind teaches that the computer receiving the heart rate data can be programmed to dial 911 in case of an emergency, it would be obvious to one of ordinary skill in the art at the time of the invention to program the computer to turn the appliances on and off according to the type of signal received from the heart monitor (see col. 11, lines 49-55) especially because some of the benefits of the smart sensor modules are minimal energy usage, as taught by Lind (see col. 10, lines 47-49 and 55-59).

29. Regarding Claims 75-76, Lind discloses that the home information transmission pathways are capable of receiving wireless transmission or electronic transmission from the monitor, the pathways wirelessly transmitting the signal to the central home control unit and the pathways wirelessly transmitting (see col. 4, lines 46-48) or electronically transmitting (see internet links, col. 7, lines 43-47) the signal to the home appliances. Although Lind does not disclose that the signal is a wake or sleep signal, Lind does

disclose that heart rate data is transferred as a signal and the heart rate data encompasses the wake or sleep signal.

Conclusion

30. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Schroeppel et al. (US Patent 6,571,121) tests heart rate variability, but not on a wrist monitor.

31. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

32. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

33. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natasha N. Patel whose telephone number is 571-272-5818. The examiner can normally be reached on M-F 8:30-5:00.

34. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on 571-272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

35. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NNP
1/11/07

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